



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration **d1329b**

June 19, 1998

Warning Letter
CHI-26-98

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

Mr. Zahid Khan, Owner
Tri-Star Instruments, Inc.
4624 W. 138th Street
Crestwood, IL 60445

Dear Mr. Khan:

During an inspection of your firm from March 12 to April 1, 1998, Investigator Matthew J. Sienko determined that your firm is an initial distributor of surgical instruments from Pakistan. Surgical instruments are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). Section 820.3(o) of the Quality System Regulation (QSR) includes initial distribution within the definition of a manufacturer and as a manufacturer you are subject to Title 21, Code of Federal Regulations (CFR).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the QSR as specified in 21 CFR, Part 820, as follows:

1. Failure to establish and maintain procedures for identifying product during all stages of receipt and distribution to prevent mix-ups. As part of the importation process, you have provided test results to our office to support the entry. Our investigation determined that your firm does not have adequate controls in place to ensure that the proper product is sampled and that the results provided to our office are for the correct entry. For example, you provided our office with test results for Adson Forceps, samples A&B, for entry 231563462-0. Those A&B subsamples were not identified to denote which lot number it represented. The manager could not identify which sample belonged with which lot number, and he could not recollect how they were sampled or even if each lot had been sampled.
2. Failure to maintain distribution records, which include the names and addresses of the initial consignee, identification and quantity of devices shipped, the date shipped and any control numbers used.
3. Failure to establish and maintain procedures for receiving, reviewing and evaluating complaints. Procedures shall ensure that all complaints are processed in a uniform and timely manner, that oral complaints are documented upon receipt and that complaints are evaluated to determine whether reporting under the Medical Device Reporting regulation is required.

Further, Mr. Sienko sampled product that was part of entry 231-5630462-0. Our samples included your Littauer Scissors 4.5" and Iris Scissors. Both of these samples were tested by our laboratory and were found to contain insufficient levels of chromium. Our analysis found one blade of the Littauer scissors contained 10.3% chromium. The Iris Scissors were found to contain 11.3% chromium. The QSR requires that you investigate the cause of nonconformities relating to product and identify the action needed to correct and prevent recurrence of the nonconformance.

This letter is not intended as an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

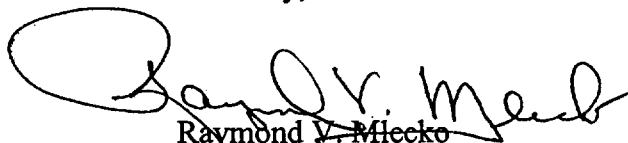
Until these violations are corrected, and FDA has documentation to establish that such corrections have been made, Federal Agencies will be advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction and/or civil penalties.

Please notify this office within 15 days of receipt of this letter, of the specific steps you will be taking to comply with our request.

Your response should be sent to Stephen D. Eich, Compliance Officer, Food and Drug Administration, 300 South Riverside Plaza, Suite 550 South, Chicago, Illinois 60606.

Sincerely,


Raymond V. Mlecko
District Director